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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,149	10/30/2003	Charles L. Byers	A325-USA	9789

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EXAMINER	
SAVAGE, JASON L	
ART UNIT	**PAPER NUMBER**
1775	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,149	BYERS ET AL.	
	Examiner	Art Unit	
	Jason L. Savage	1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040116, 20050531*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites in lines 10-13 that the ceramic may be selected from a variety of ceramic materials; however, in line 15, Applicant recites the ceramic is selected to be the specific ceramic of tetragonal zirconia polycrystal. It is unclear if Applicant intends the claim limitations to include any of the listed ceramics in the claim or if it is intended to only be limited to tetragonal zirconia polycrystal. For purposes of examination, the claim has been treated as meaning that the ceramic may be selected from any of the ceramics listed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-10, 15-16, 18-21, 27-28, 34-35 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lasater (US 6,221,513) in view of Bealka et al (US 6,586,675).

Lasater teaches a hermetically sealed assembly suitable for use in implantable medical devices which comprises a ceramic part bonded to a metal part using a titanium-nickel interlayer to join the parts (col. 1, ln. 7-13). Lasater further teaches the sealed assembly is one which comprises a metallic pin **22** which is joined to a ceramic **24** which is sealed by the titanium-nickel interlayer **32** (col. 7, ln. 26-42). However, Lasater is silent to the metal member **22** being a noble metal.

Bealka teaches sealed medical implant devices which comprise biocompatible materials (col. 1, ln. 9-14). Bealka further the sealed assembly comprises a metallic pin **20** which is joined to a ceramic **16** with sealing material **18** (col. 5, ln. 4-37). Bealka further teaches that as materials suitable for use as the metal pin member **20** are noble metals as well as other metals such as titanium.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have recognized that the other metal pin materials such as the noble metals taught by Bealka could be suitable for use as the metal pin in the assembly of Lasater with a reasonable expectation of success.

Regarding claim 2, Lasater teaches the assemblies are suitable for use in implantable medical devices (col. 1, ln. 7-14).

Regarding claims 3-4, Lasater teaches the interlayer composition may be 50-50 and 65-35 titanium-nickel (col. 2, ln. 54-64). Although the teaching of 35% nickel of

Lasater is greater than the 33% claimed, it would have been obvious to one of ordinary skill in the art to have recognized that other concentrations of the interlayer materials could be employed with a reasonable expectation of success. Absent a teaching of the criticality of the nickel concentration being 33%, it would not provide a patentable distinction over the prior art.

Regarding claims 6 and 19, Lasater teaches that a variety of ceramics may be used for the ceramic part including the ceramics claimed by Applicant (col. 2, ln. 24-41).

Regarding claim 7, Bealka teaches that noble metals of platinum and iridium are suitable for use as the metal part (col. 5, ln. 7-18).

Regarding claim 8, the interlayer of titanium and nickel would meet the limitation that the metals can form a liquidus to create a bond between the parts since titanium and nickel are known to form liquidus eutectics.

Regarding claim 9, Lasater teaches the composite is heated to a temperature greater than the liquidus eutectic forming temperature wherein the temperature does not exceed the melting point of the metal parts (col. 3, ln. 13-33).

Regarding claims 10 and 21, Lasater further teaches that the interlayer thickness is preferably between 0.003-0.004 inches.

Regarding claim 15, Lasater teaches the assembly is hermetically sealed (col. 1, ln. 7-14).

Regarding claim 16, Lasater teaches that the assembly is formed in a non-reactive atmosphere such as a vacuum by heating to a bonding temperature between the liquidus temperature but below the melting point of the metal part. Lasater further

teaches the assembly is held at the bonding temperature until the seal is formed and then the assembly is cooled (col. 6, ln. 43-64). Regarding the limitation that a force is applied to compress the assembly, Lasater teaches that it is preferably to apply a force to compress the assembly while treating the assembly by heating and cooling (col. 8, ln. 57-60).

Regarding claim 18, Lasater teaches that a force of 2000 psi may be applied to the assembly which meets the claim limitation (col. 8, ln. 57-64). In the alternative, it would have been obvious to one of ordinary skill in the art to have used any pressure, including pressures below the range taught by Lasater, so long as the formed assembly still exhibited desirably properties such as being hermetically sealed. Absent a teaching of the criticality or showing of unexpected results, the claimed pressure would not provide a patentable distinction over the prior art.

Regarding claims 27-28, Lasater teaches the bonding temperature is held at a temperature between 1000-1100 °C for several minutes to several hours (col. 6, ln. 43-64).

Regarding claim 34, Lasater as modified by Bealka teaches all of the claim limitations wherein an assembly for use with living tissue is formed by interposing an interlayer of nickel and titanium between a ceramic part and a noble metal. Then the assembly is treated by applying a force of 2000 psi to compress the assembly while heating at a temperature between 1000-1100°C, all of which was set forth above.

Regarding the limitation that the ceramic is of the claimed materials, Lasater teaches the same ceramic materials may be used including tetragonal zirconia polycrystal.

Regarding claims 35, and 37-38, Bealka teaches the metal part of the claimed noble metals and Lasater teaches interlayer may be nickel and titanium mixtures of equal proportions of the materials and wherein the interlayer may comprise twice as much titanium as nickel.

Claims 2, 17, 31-33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lasater (US 6,221,513) in view of either Bealka et al (US 6,586,675) as applied to claims 1, 3-10, 15-16, 18-21, 27-28, 34-35 and 37-38 above, further in view of Hirano (US 5,028,495).

Lasater and Bealka teach what is set forth above however it is silent to the interlayer being in the form of a laminate. Hirano teaches laminate composite bonding foils of titanium and nickel which are suitable for use for joining ceramics and metals. Hirano further teaches that the laminate foils provide for reduced cost and improved efficiency in joining the ceramic and metal parts (col. 2, ln. 7-21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed a laminate of titanium and nickel such as taught by Hirano in the assembly of Lasater in view of Bealka in order to have reduced achieve reduced costs and to improve the efficiency of joining the materials.

Regarding claims 32-33, Lasater teaches the interlayer may comprise a 50-50% mixture and 35-65% mixture of nickel and titanium (col. 2, ln. 54-62). Therefore it would have been obvious to have used laminated foils having the same concentrations of materials.

Claims 11-14, 22-26, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lasater (US 6,221,513) in view of either Bealka et al (US 6,586,675) as applied to claims 1, 3-10, 15-16, 18-21, 27-28, 34-35 and 37-38 above, further in view of Fey et al. (US 6,521,350).

The references teach what is set forth above but are silent to some of the claim limitations. Fey teaches an assembly comprising a ceramic and metal which are bonded by an interlayer (col. 1, ln. 15-27).

Regarding claims 11-14 and 22-25, Fey teaches teaches that the interlayer may be a thin coating that is applied to either of the parts to be bonded and that the interlayer material may be applied by any of a variety of chemical processes such as electroless plating and electroplating, or by any of a variety of thermal processes such as sputtering, evaporating, or ion beam enhanced deposition. Interlayer material 8 may also be applied as a thin coating of metallic beads or metallic powder (col. 3, ln. 26-41).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have recognized that the interlayer material of Lasater could be applied by a wide variety of methods such as those taught by Fey with a reasonable expectation of success.

Regarding claim 26, Lasater is silent to the vacuum conditions. Fey teaches that the use of a vacuum of 10^{-6} to 10^{-7} torr is suitable for use in forming the composite assembly (col. 3, ln. 57-67). It would have been obvious to one of ordinary skill in the art to have used the vacuum conditions recited by Fey in the process of Lasater since Lasater fails to teach a desired level of vacuum.

Regarding claims 29-30, Lasater is silent to cleaning the assembly after forming. However, Fey teaches that the assembly is preferably cleaned by acid bath in order to assure removal of unwanted materials such as metal salts (col. 4, ln. 14-26). It would have been obvious to one of ordinary skill in the art to have employed a cleaning treatment when forming the assembly of Lasater in order to have insured all undesirable materials were removed prior to it being used in living tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason L. Savage whose telephone number is 571-272-1542. The examiner can normally be reached on M-F 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on 571-272-1535. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason Savage
6-27-05

DEBORAH JONES
SUPERVISORY PATENT EXAMINER